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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,802	01/11/2001	Mario Rosario Carlone JR.	1334	9354

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/23/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,802

Applicant(s)

Carlone et al

Examiner

FOX

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

3/11/03

- ☒ Responsive to communication(s) filed on _____
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 2, 4-10, 15, 16, 21, 23-29, 37-43, 50-57 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 1, 2, 4-8, 21, 23-27, 40 is/are allowed.
- ☒ Claim(s) 9, 10, 15, 16, 28, 29, 37-39, 41-43, 50-57 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 11 March 2003 has overcome all outstanding rejections under 35 USC 112, second paragraph; the rejections of claim 40 under 35 USC 112, first paragraph; and the art rejection under 35 USC 102/103.

Claims 51 and 55-57 (newly submitted) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51, 55 and dependents are indefinite in their use of improper Markush terminology. Specifically, --selected-- should be inserted before "from" in line 3 of claim 51 and line 2 of claim 55. In addition, "a" in line 3 of claim 51 should be replaced with --the--. See MPEP 2173.05(h).

The amendment filed 11 March 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Table A comprising SSR data, inserted on page 16 of the specification at line 23.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 43 and 50-53 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 43 recites "at least 50% genetic contribution from". Claims 50- 52 and dependents recite "backcross conversion" maize plants. There is no basis in the specification for either term. Accordingly, these terms constitute NEW MATTER.

Claims 9-10, 15-16, 28-29, 37-39, 41-43 and new claims 50-54 and 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last Office action on pages 3-5 for claims 3, 9-20, 22, 28-32, 34-44 and 47-49.

Claims 9-10, 15-16, 28-29, 37-39, 41-43 and new claims 50-54 and 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in the last Office action on pages 6-8 for claims 3, 9-20, 22, 28-32, 34-44 and 47-49.

The claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a maize plant with all of the genetic or morphological characteristics of the claimed inbred, or methods of its use to obtain hybrid plants with at least 50% of the genetic component of the exemplified inbred.

Claims 1-2, 4-8, 21, 23-27 and 40 are allowed.

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Applicant's arguments filed 11 March 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the guidance in the specification regarding available transgenes and methods for their introduction, the knowledge of and widespread use of backcrossing techniques by those skilled in the art to introduce traits of interest into elite breeding lines, the failure of the introduction of a few genes to materially prevent one skilled in the art from identifying the transformed or backcrossed plant as being derived from the exemplified inbred, the ability of the skilled artisan to identify via molecular techniques the exemplified inbred as the source of any backcrossed plant or hybrid plant (as evidenced by the Rule 132 declarations executed by Smith and Bhatramakki, following the SSR technique taught by Berry et al appended hereto), the amendment of the instant specification to include the SSR data for the exemplified inbred wherein such an amendment is not new matter per *Ex parte Marsili*, 214 USPQ 904 (Bd. Pat. App. Int. 1979), the permissibility of a claim to an F1 hybrid made with a deposited inbred as taught by *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 50 USPQ 2d 1865, 1873 (S. Ct. 2001), the description of descendant plants by virtue of their containing at least 50% of their genomic contribution from the exemplified inbred, the various phenotypic characteristics of the exemplified inbred, the ability of a deposit to provide an adequate written description as taught by *Enzo vs. Gen-Probe*, 63 USPQ2d 1609, (Fed. Cir.), and the adequate description in the specification of a method to identify contaminating inbred seeds in a bag of hybrid seed.

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Regarding transgenes, the Examiner maintains that claims limited to the use of particular classes of transgenes would be adequately described, but reiterates that claims broadly drawn to methods of using any unspecified transgene remain inadequately described. The specification fails to provide any guidance for all transgenes, conserved sequences found in all transgenes, or any correlation of any putative conserved sequences with function, as required by the Revised Written Description Guidelines, Fed. Reg. Vol. 66, No. 4, issued Friday, January 5, 2001, pages 1099-1111. See also MPEP 2163.

Regarding backcrossing, the Examiner maintains that while the technique may be used in the art for the introduction of individual desired traits, it results in the introduction of unwanted linked genes and traits encoded thereby, as established previously by the Examiner and as admitted by Applicant (see, e.g., page 13 of the amendment of 11 March 2003, middle paragraph, where 2% of the recurrent parent's genome was comprised of foreign genes from the donor parent). Since Applicant's patentable invention is the unique collection of genes at every locus of the exemplified inbred, and the unique collection of traits encoded thereby, such backcross techniques would generate corn plants substantially different from the exemplified inbred. Applicant's assertions that the genetic contribution of the donor parent is not substantial are not probative, particularly in view of the failure of Applicant to identify the genes responsible for each trait exhibited by the exemplified inbred, the failure of Applicant's specification to identify the genetic component of the exemplified inbred at every locus, and the lack of uniqueness of each *individual* trait exhibited by the exemplified inbred.

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Regarding the use of molecular techniques to identify a fingerprint of the exemplified inbred, the Examiner maintains that the instant specification does not provide adequate information for such techniques. Page 16 of the specification states that isozymes and RFLPs are the most widely used molecular markers. No detailed methodology is provided regarding the use of any molecular marker technique, particularly the SSR markers utilized in the Rule 132 declarations and taught by Berry et al, published in 2002, well after the effective filing date.

Regarding the amendment of the instant specification to introduce SSR fingerprint data, the Examiner maintains that such an amendment is NEW MATTER, and that *Marsili* is not controlling, as different fact patterns were involved. On page 905 of *Marsili*, penultimate paragraph, the Court states that the amendment in *Marsili* was not new matter because it merely constituted a *correction* of a *previously submitted* description of a compound, which is permissible; rather than "the question of *adding* characteristics not previously mentioned" [emphasis in the original], which remains impermissible per *Ex parte Fox* and *Ex parte Davisson & Finlay* cited by the Examiner in *Marsili*. In *Marsili*, the specification already disclosed a chemical structure for the claimed chemical compound, while the amendment merely corrected an error in the structure. In the instant application, no molecular data of any kind were presented, much less any SSR data, so that the amendment to subsequently introduce them constitutes the impermissible addition of "characteristics not previously mentioned".

Regarding *J.E.M.*, the Supreme Court was solely ruling on the patentability of plants under 35 USC 101, rather than 35 USC 112, first paragraph. The Court also stated at page 1873

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that "to obtain a utility patent, a breeder must describe the plant with sufficient specificity to enable others to 'make and use' the invention after the patent term expires. Section 112." In addition, the Court stated, "The description requirement for plants includes a deposit of biological material, for example seed, and mandates that such material be accessible to the public". A reasonable interpretation of this statement is that a deposit is required for each claimed embodiment. Thus, a deposit of the exemplified inbred line would not adequately describe a multitude of hybrids or backcross progeny derived therefrom.

Regarding the 50% derivation language, the Examiner maintains that no attempt was made to genetically characterize the exemplified inbred at any particular genetic locus. The inbred was only characterized based upon a collection of particular traits, wherein the individual traits were not unique to the claimed inbred either in genetic control or level of expression. In the absence of any characterization of the genotype of the exemplified inbred, plants containing only half of its genome are also inadequately described.

Regarding *Enzo*, the Examiner maintains that while claims limited to the deposited inbred are adequately described, claims broadly drawn to any other variant or descendant thereof comprising additional genes are not. Note that the Federal Circuit in *Enzo* remanded the case to the District Court to decide this issue. Furthermore, the Examiner has demonstrated that the introgression of a single trait of interest would in fact result in the introduction of additional, uncharacterized genetic material.

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Regarding the claimed method of identifying contaminating inbred seeds in a bag of hybrid seeds, the Examiner maintains that these claims remain drawn to the use of an inadequately described product (the hybrid seed produced by outcrossing with any of a multitude of uncharacterized inbreds), and so are themselves inadequately described per the Written Description Guidelines, as discussed previously.

Applicant urges that the enablement rejection is improper, given the recognition of "essentially derived" varieties by UPOV. The Examiner maintains that the issue at hand is the enablement of claims under 35 USC 112, first paragraph, for which a U.S. patent is sought under 35 USC 101, rather than an application for a plant variety protection certificate or equivalent under UPOV.

Applicant further urges that the references cited by the Examiner in his enablement rejection do not support his position. Applicant urges that Hunsperger et al do teach some successes, that the instant specification suggests the construction of genetic maps, and that Kraft et al do not teach the general unpredictability inherent in the process. The Examiner maintains that Hunsperger et al teach failures as well as successes, while Applicant does not attempt or reduce to practice any single gene conversion. Kraft et al do teach the unpredictability inherent in constructing genetic maps based upon molecular marker data, even when the parent plants are adequately characterized, thus refuting Applicant's assertions that such maps may be constructed here. Furthermore, it is noted that the instantly exemplified inbred is NOT adequately

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characterized, as stated above, and that none of the other non-exemplified parents embraced by the broad claims are characterized at all.

In addition, Applicant has demonstrated the unpredictability inherent in the maize breeding process in their admission on page 7 of the specification, top paragraph, that

[A] breeder of ordinary skill cannot predict the genotype, how that genotype will interact with various climatic conditions or the resulting phenotypes of the developing lines, except perhaps in a very broad and general fashion. A breeder of ordinary skill in the art would also be unable to recreate the same line twice from the very same original parents as the breeder is unable to direct how the genomes combine or how they will interact with the environmental conditions.

Finally, Applicant urges the Examiner to apply the arguments regarding the written description rejection to the enablement rejection as well. Applicant relies upon SSR data and techniques disclosed by Berry et al (2002) in order to demonstrate that molecular methods for identifying descendants of the exemplified inbred were available to the skilled artisan. The Examiner maintains that the instant specification as originally filed is silent regarding any detailed SSR methodology or any SSR data, and that Berry et al (2002) was not cited in the specification, much less incorporated by reference. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. See also *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 20, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

